DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 19,2014

Actegy, Ltd.
C/O Dr. John J. Smith
Hogan Lovells US LLP
Regulatory Counsel
Columbia Square
555 13th Street, NW
Washington, DC 20004

Re: K140772
Trade/Device Name: Aerosure Medic
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive spirometer
Regulatory Class: II
Product Code: BWF
Dated: December 2, 2014
Received: December 2, 2014

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

Device Name

Aerosure Medic

Indications for Use *(Describe)*

Aerosure is indicated for use as a Positive Expiratory Pressure (PEP) Device.

- The use of Aerosure improves clearance of secretions
- The use of Aerosure may reduce the need for postural drainage
- Aerosure facilitates opening of airways in patients with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems
- Aerosure may be used to prevent or reverse atelectasis
- Aerosure may also be useful in the removal of mucus from the lungs of patients who have chronic bronchitis or bronchiectasis

Aerosure is intended for patients age 21 and above with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems, and patients with atelectasis. All patients must be capable of following instructions for Positive Expiratory Pressure Therapy.

Aerosure may be used in hospital as well as the home after a period of training.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Actegy's Aerosure Medic

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Actegy Ltd.
8 Queen Square, Ascot Business Park
Lyndhurst Road
Ascot
Berkshire SL5 9FE
UK

Phone: +44(0) 1344 636 940
Facsimile: +44(0) 8452 255 612

Contact Person: Angie Glover
Date Prepared: December 18, 2014

Name of Device and Name/Address of Sponsor

Aerosure Medic

Actegy Ltd.
8 Queen Square, Ascot Business Park
Lyndhurst Road
Ascot
Berkshire SL5 9FE
UK

Common or Usual Name

Oscillatory positive expiratory pressure devices (OPEP)

Classification Name

Incentive spirometer, 21 C.F.R. §868.5690, Product code BWF

Powered percussor, 21 C.F.R. § 868.5665, Product code BYI

Predicate Devices

Flutter D (Clement Clarke), K972859; Acapella (Smiths Medical), K002768; Roadrunner (DHD), K991561.

Intended Use / Indications for Use

Aerosure is indicated for use as a Positive Expiratory Pressure (PEP) Device.

- The use of Aerosure improves clearance of secretions
- The use of Aerosure may reduce the need for postural drainage
- Aerosure facilitates opening of airways in patients with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems
- Aerosure may be used to prevent or reverse atelectasis
- Aerosure may also be useful in the removal of mucus from the lungs of patients who have chronic bronchitis or bronchiectasis

Aerosure is intended for patients age 21 and above with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems, and patients with atelectasis. All patients must be capable of following instructions for Positive Expiratory Pressure Therapy.

Aerosure may be used in hospital as well as the home after a period of training.

Technological Characteristics

The Aerosure Medic consists of an electrically powered rotary valve mechanism which acts as a means of restricting the user's inhalation and exhalation efforts and generating vibration of the respiratory tree, thus facilitating the removal of mucus from the lungs.

Performance Data

Biocompatibility (ISO 10993), electromagnetic compatibility (IEC 60601-1-2), medical device safety testing (IEC 60601-1), and other performance testing were conducted. In all instances, the Aerosure Medic functioned as intended and the results observed were as expected.

To support the cleaning instructions, cleaning and ingress protection testing was conducted to demonstrate that reasonably expected cleaning of the device would not have an effect of performance or safety. The results verified that there was no depreciation in performance or safety. In addition, in order to verify the Aerosure Medic ingress protection rating of IP45 [IEC60529], testing was conducted to investigate the effects of expected in-use exposure to water. The results verified that there was no water ingress into the device and that the device function was normal after exposure.

Actegy conducted functional testing as part of the design verification process which demonstrated the Aerosure Medic device met its specifications. In addition, the company conducted bench testing comparing the performance characteristics for the Aerosure Medic and the legally marketed predicates. The results showed that all of the devices have directly comparable basic characteristics and substantially similar output specifications.

Finally, Actegy conducted usability testing to demonstrate the safe use of the device in the target user population, i.e., lay persons. The Aerosure Medic summative protocol design, conduct, and analysis followed FDA's human factors draft guidance for industry entitled, *Applying Human Factors and Usability Engineering to Optimize Medical Device Design* (June 22, 2011). Based on the findings of this study, it was concluded that Aerosure Medic is reasonably safe and effective for the intended users, uses and use environments.

Substantial Equivalence

The Aerosure Medic is substantially equivalent to the predicated devices.

The Aerosure Medic has substantially equivalent intended uses, indications, technological characteristics and principles of operation as its predicate devices. The Aerosure Medic differs from the predicate devices in terms of certain technological characteristics (minor differences in construction, battery and motor-driven vs. manual power, minor differences in occlusion mechanism, weight and dimensions).

Performance bench test data demonstrate that the Aerosure Medic is substantially equivalent to the predicate devices. Thus, the Aerosure Medic is substantially equivalent.

Conclusion

The Aerosure Medic is substantially equivalent to the predicate devices Flutter D (K972859), Acapella (K002768) and Roadrunner (K991561).

Basic Unit characteristics				
	Aerosure Medic	Roadrunner	Flutter D	Acapella
510k number	TBD	K991561	K972859	K002768,
Manufacturer	Actegy Ltd.	DHD Healthcare	Clement Clarke (Axcan Scandipharm)	Smiths Medical
Intended use	Aerosure is indicated for use as a Positive Expiratory Pressure (PEP) Device. • The use of Aerosure improves clearance of secretions • The use of Aerosure may reduce the need for postural drainage • Aerosure facilitates opening of airways in patients with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems • Aerosure may be used to prevent or reverse atelectasis • Aerosure may also be useful in the removal of mucus from the lungs of patients who have chronic bronchitis or bronchiectasis Aerosure is intended for patients age 21 and above with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems, and patients with atelectasis. All patients must be capable of following instructions for Positive Expiratory Pressure Therapy. Aerosure may be used in hospital as well as the home after a period of training.	1 - Purpose: The DHD Roadrunner is indicated for use as a Positive Expiratory Pressure (PEP) Device. 2 - Claims: • The use of DHD Roadrunner improves clearance of secretions • The use of DHD Roadrunner may reduce the need for postural drainage • DHD Roadrunner facilitates opening of airways in patients with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems • The DHD Roadrunner may be used to prevent or reverse atelectasis 3 - Target Patient Population Patients with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems, and patients with atelectasis. All patients must be capable of following instructions for Positive Expiratory Pressure Therapy. 4 - Intended Environment for Use • Labeling reflects the statement: “Federal (USA) Law restricts this device to sale by or on the order of a physician.” • May be used in hospital as well as the home after a period of training.	The efficacy of the Flutter 4D as a mucus clearance device for cystic fibrosis patients is based on its ability to 1) vibrate the airways (which loosens mucus from the airway walls), 2) intermittently increase endobronchial pressure (to maintain the patency of airways during exhalation, so that mucus does not become trapped as it moves up the airways), and 3) accelerate expiratory airflow (to facilitate the upward movement of mucus through the airways so that it can be more easily coughed out). FlutterD may also be useful in the removal of mucus from the lungs of patients who have chronic bronchitis or bronchiectasis and in conjunction with a medical need for Positive Expiratory Pressure (PEP) Therapy.	Acapella is intended for use as a Positive Expiratory Pressure (PEP) device. It may also be used simultaneously with nebulized aerosol drug delivery.
Device	Aerosure is a small, battery powered device. It produces a rapidly alternating occlusion of airflow as	Positive Expiratory Pressure and vibration feature	The Flutter®D is a small, single use, hand held device expiration	Acapella is a small, single use, hand held secretion

Description	a user breathes through the replaceable valve head (containing the powered rotating vane mechanism) which creates a general increase in resistance to breathing and a vibration of the respiratory tree and the associated structures, including the musculature. Frequency is adjusted by switching modes.	Use when both inhale and exhale Adjust frequency with knob Manually powered device.	resistance device. consisting of a hardened plastic mouthpiece at one end, a plastic cover with an opening at the other end, and a valve on the inside created by a high density steel ball resting in a plastic circular cone. Exhalation through the device causes vibrations to loosen mucus from the airways. The resistance is increased by tilting the device	clearance and lung expansion plastic mechanical device that creates vibrating positive expiratory pressure when a patient exhales through the device via a vibrating orifice mechanism. The resistance is adjusted via the rotating dial.
Software/ Firmware/ Microprocessor control	Yes	No	No	No
Power source	3 cell NiMH rechargeable battery (nominal 3.6V) to drive the motor. The charger operates normally with a power supply range of 110~240 V / 50Hz	Inhalation & Exhalation – manual, mechanical powered device	Exhalation – manual, mechanical powered device	Inhalation & Exhalation – manual, mechanical powered device
Compliance with Voluntary standards	ISO 10993; IEC 60601-1-2; IEC 60601-1	Unknown	Unknown	Unknown
Weight	195g	Unknown	86g	89g
Dimensions	45x96x149	Unknown	90x56x44	172x60x58
Housing materials and construction	Plastic mouldings	Unknown	Plastic mouldings	Plastic mouldings